DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service

Food and Drug Administration
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February 26, 1999

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 99-08

Michael A. Josephson, Owner
Josephson's Smokehouse & Dock
106 Marine Drive
Astoria, Oregon 97103

WARNING LETTER

Dear Mr. Josephson:

On October 21-23 and November 4, 1998, FDA Investigators conducted an inspection of your firm located at 106 Marine Drive, Astoria, Oregon. At the conclusion of the inspection, you were presented with a Form FDA 483 listing serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (HACCP Regulation). A copy of the Form FDA 483 is enclosed for your review. By virtue of these deficiencies, the hot and cold smoked and jerky seafood products, packaged in vacuum packed bags and stored, refrigerated, or frozen, processed at your facility, are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) and 21 CFR Part 123.

1. You could not provide documentation to our investigators that demonstrates your processes for manufacturing smoked seafood products are adequate to achieve a water phase salt (wps) of 3.5% or greater in the finished product, in order to control the formation of *Clostridium botulinum* toxin. 21 CFR Part 123.8(a) requires you to verify your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur. *Clostridium botulinum* toxin formation is a food safety hazard that is reasonably likely to occur. This means your firm needs to establish your processes, including brining and smoking, and other factors that may affect the wps of the finished products, are sufficient to achieve a wps of 3.5% or greater, and thus control the food safety hazard of *Clostridium botulinum* toxin formation.

2. We reviewed your hot smoked fish records, and found at least four production dates where your process did not meet the critical limit of [redacted] hours of smoking. Additionally, the records were reviewed and the review did not appear to find or generate correction of these deviations. In fact, the total time duration allotted on the record is [redacted] hours to [redacted] hours, so it does not appear possible you could ever meet the critical limit you have set for hot smoked fish. 21 CFR

Part 123.7(a) requires you to take a corrective action whenever a deviation from a critical limit occurs. However, we reviewed your records and there was no evidence corrective action was taken.

The total smoking times for four production dates were:

a. 8/25/98 hours
b. 9/17/98 hours
c. 9/23/98 hours
d. 10/21/98 hours

3. Under the critical limit for the cooling before and after smoking, your HACCP plan lists "maximum cooler temperature"; however, no temperature is actually identified. 21 CFR Part 123.6(c)(3) requires you to list critical limits that must be met at each critical control point.

Your HACCP plans for hot and cold smoked products list a temperature recorder chart as the monitoring record to be maintained for the cooler critical control point. Our investigators found that since June 1, 1998, you have only maintained this record three times.

4. Under critical limits in your HACCP plans for hot smoked, cold smoked, and jerky products, you reference a process schedule, a document identified as "JOSEPHSON'S SMOKEHOUSE CRITICAL LIMITS". The document lists critical limits for brining, curing, smoking, and/or cooking as applicable for hot and cold smoked products. The document does not list any critical limits for jerky products. Under 21 CFR Part 123.6(c)(3), you are required to list critical limits that must be met at each critical control point. The FDA allows firms to reference critical limits in another document, such as a process schedule, to alleviate redundant paperwork. However, in this case, your firm failed to list the critical limits in the referenced document, which raises serious concerns about the process controls your firm claims to have in place for your jerky products.

5. In your HACCP plans, you identified temperature critical limits, specifically listed in your process schedule, that need to be met. Several temperatures, at varying stages of the process, were identified as critical; however, our investigators found, on several production logs, you were not taking internal or external temperatures to monitor whether or not the critical limit was met. 21 CFR Part 123.6(c)(7) requires you to provide for a record keeping system that documents the monitoring of critical control points. The records must contain the actual values and observations obtained during monitoring. Though it appears you have created a record keeping system, you are not consistently maintaining and/or completely filling out those records.

6. Our investigators observed an employee roll two racks of smoked salmon across a wet floor, through puddles of water, and into the cooler. The smoked fish on the bottom layer of the rack was approximately one-quarter of an inch off of the floor. This practice creates the potential for cross contamination, should water from the puddles splash onto the pieces of smoked fish as the cart is rolled through the puddle. 21 CFR Part 123.11(b)(3) requires you to monitor for the prevention of cross contamination.

7. Your HACCP plan addresses the control of the fishery product storage-step following the smoke-step. However, no control is provided for the period of time the product is held between the smoking process and storage where the product is not refrigerated. For the hot-smoked product, *Staphylococcus aureus* and histamine hazards are probably removed from consideration at this time, but the food safety hazards *Clostridium botulinum* type A and proteolytic types B and F would still exist, especially considering the heat shock provided by the hot smoking temperatures.

8. Further, the plan should include appropriate critical limits, as required by 21 CFR Part 123.6(c)(3), for the maximum temperature during the dry salting process in the cold-smoked plan and for the maximum temperature during cold smoking.

9. There has been no study to relate the temperature of the cooler to the rate of cooling, after either the hot smoking or the cold smoking step, in order to assure control of the hazard associated with *Clostridium botulinum* toxin formation as required by 21 CFR Part 123.16.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Other deficiencies with your HACCP program have also been noted. These deficiencies are not considered to be serious deviations from the HACCP Regulation; however, it is important that you make the necessary corrections.

10. Another part of verification, under 21 CFR Part 123.8(a), is ensuring your HACCP plan is effectively implemented. This means your firm must follow practices identified in your HACCP plan, or reevaluate your HACCP plan and ensure it reflects your firm's practices.

11. Of further concern is records are signed and dated as being reviewed; however, your record review did not detect the errors described under observation number two of this letter. 21 CFR Part 123.8(a)(3)(i) requires critical control point records be reviewed by a HACCP trained individual. The purpose of this review is to ensure the document is complete and the values are within critical limits.

12. Calibration procedures for the smoker thermometers were not listed in the HACCP plans for any of the products manufactured by your firm, nor does it appear you calibrated the smoker thermometers. Your HACCP plan did list weekly calibration procedures for the cooler and freezer thermometers; however, according to your calibration records, you have only calibrated those thermometers three times since June 1, 1998. As part of verification, 21 CFR Part 123.8(a)(2)(ii) requires you to calibrate process monitoring instruments. Additionally, under 21 CFR Part 123.8(d), you are required to maintain a record of any calibration functions performed. Another part of verification, under 21 CFR Part 123.8(a), is ensuring your HACCP plan is effectively implemented.

13. Your HACCP plans do not include calibration of the scale used to determine weight loss in the product after drying.

14. Water phase salt analyses would be more appropriate if performed quarterly rather than annually.

15. The data logger necessary to measure internal temperatures of product during the smoking process should be calibrated daily.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay, and the time within which the corrections will be completed. Pertinent sections of the Act and the Regulations are enclosed for your review. Your reply relating to these concerns should be addressed to the Food and Drug Administration, Attention: Janelle K. Main, Compliance Officer, P.O. Box 3012, Bothell, Washington 98041-3012.

Sincerely,

Miriam R. Burbach for
Roger L. Lowell
District Director